28 January 2016

Submission of comments on draft ICH Guideline for good clinical practice E6(R2) (EMA/CHMP/ICH/135/1995)

Comments from:

Name of organisation or individual
ACRO (Association of Clinical Research Organizations)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	The Association of Clinical Research Organizations (ACRO) represents the world's leading, global clinical research organizations (CROs). Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices – from discovery, pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. With more than 110,000 employees engaged in research activities around the world (including 30,000 in Europe), ACRO advances clinical outsourcing to improve the quality, efficiency and safety of biomedical research. Each year, ACRO member companies conduct more than 9,000 clinical trials involving nearly two million research participants in 142 countries. On average, each of our member companies works with more than 500 research sponsors annually. ACRO welcomes and supports the proposed revisions to the ICH good clinical practice (GCP) guideline. ACRO particularly welcomes (1) the clarification of the supervisory responsibilities of the investigator and the maintenance of source documents and trial records with the inclusion of the requirement for records to be “complete”, (2) the flexibility to the approach to	

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	maintenance of data generated by the investigator in a system that is not under the exclusive control of the sponsor, (3) the introduction of a risk-based approach to clinical trial management and monitoring to encourage the implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording and reporting, while continuing to ensure human subject protection and data integrity, and (4) the additional formal requirement for root cause analysis (RCA) and implementation of corrective and preventive actions (CAPAs). Clarification is requested, however, on when to implement CAPAs. ACRO notes that, under the heading of “Noncompliance”, the draft guideline states that “when significant noncompliance is discovered, the sponsor should perform a root cause analysis and implement appropriate corrective and preventive actions.” ACRO fully supports this statement. However, based on the extensive experience of ACRO member companies in managing clinical trials on behalf of a wide range of sponsor organisations, ACRO members have noted that sponsors vary significantly in their approaches to use of a formal CAPA process; some sponsors will raise CAPAs formally for everything from minor deviations to significant noncompliances whereas others limit their use to the latter. Consequently, ACRO	

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	recommends that text should be added to the guideline to clarify when and how a formal CAPA procedure should be used. Additionally, there are several further topics, reflecting developments and experience in clinical trial management, that ACRO believes should be included within the guideline in order to deliver additional harmonisation on these points. While noting that standards regarding electronic records and essential documents intended to increase clinical trial quality and efficiency have also been updated to reflect developments since the last revision of the guideline, it is ACRO's view that the current revision does not sufficiently address the implications of more recent developments in information technology such as the use of electronic signatures, electronic informed consent, increased use of cloud computing systems, and the development and use of mobile apps and the use of "bring your own devices" for the collection of clinical trial data. ACRO therefore recommends that additional text is added to the guideline in order to establish clarity on these important aspects of GCP in the current clinical trials environment. Finally, because the draft guideline issued for comment by the European Medicines Agency (EMA) was	

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	reformatted from the original ICH draft -- resulting in changes to the line numbers -- ACRO has included both the “ICH” (meaning the original ICH draft guideline) line numbers and the “EMA” (meaning the reformatted document published by the EMA) line numbers so that ACRO’s comments may be linked back to either draft document.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
ICH 31 – 314 EMA 189 - 458		Comment: Definitions relevant to the increasing use of information technology in clinical trials have not been included in the Glossary. ACRO recommends that they are added. Proposed change (if any): Add definitions of the following to the Glossary: electronic source (eSource), electronic informed consent (eConsent), electronic signatures (eSignatures), electronic data capture (eDC), electronic signatures/data stamps.	
ICH 82 - 85 EMA 236 - 239		Comment: The definition of a certified copy makes no distinction between documents verified by a dated signature on each document and documents verified by means of a batch process and confirmed by a dated signature. Given the disproportionate burden that verification of each individual document by dated signature places on clinical trial investigators, ACRO recommends that the text should clarify that a suitable documented procedure may be used for batch verification of documents. Additionally, the term “attributes” includes, for example, colour, which means that photocopies or scans should have the same look and feel as the original. However, technology may not be available at an investigator site to ensure this. Further, it is unlikely to be possible (and unnecessary) for all attributes, e.g. pH of the paper used, to be replicated. Guidance should therefore be provided to allow	

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		for attesting validity of content when not all attributes are the same, in order not to ignore the correctness of the content when format, e.g. of a coloured log, is different. Also, as the text relates to both paper and electronic certified copies, ACRO recommends that more practical guidance is given on the criteria for an electronic certified copy. Currently, there is no recognition of electronic signatures (e.g. a scanned and uploaded document, electronically signed by the uploader/scanner) in the context of certified copies. ACRO also recommends including here the statement currently in ICH line 1703 (EMA line 1931) that “When a copy is used to replace an original document, the copy should fulfill the requirements for certified copies.” Proposed change (if any): Add text to clarify that a suitable documented procedure may be used for batch verification of certified copies, to provide guidance for attesting validity of content when not all attributes are the same, and to provide more practical guidance on criteria for an electronic certified copy. Also, include here the statement “When a copy is used to replace an original document, the copy should fulfill the requirements for certified copies.”	
Between ICH lines 129 and 130		Comment: ACRO recommends that a definition of what constitutes an electronic signature in the context of GCP should be added to the guideline to provide global clarity on	

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Between EMA lines 282 and 283		the type and format of a GCP-acceptable electronic signature, especially for e-consent. In addition, electronic systems can automatically and accurately date consent forms. This addition of an electronic date stamp during the signature process should be considered equivalent to “personal” dating of the consent form. Proposed change (if any): Add the following definition of an electronic signature, consistent with 21 CFR 11: “Electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.” Also, clarify that the addition of an electronic date stamp during the signature process may be considered equivalent to “personal” dating of the consent form.	
ICH 206 - 213 EMA 355 - 361		ACRO recommends adding definitions for centralized monitoring and for source data in the context of centralized monitoring. Also, as the monitoring report now refers to centralized monitoring, ACRO recommends that the guidance is expanded to include expectations for reporting/documenting centralized monitoring activities (which may be remote, ad hoc, and/or real time checks), especially for documenting activities performed real time. Proposed Change (if any): Add definitions for centralized	

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		monitoring and source data, and include guidance on reporting/documenting centralized monitoring activities.	
ICH 209 – 213 EMA 357 - 361		Comment: It is not clear whether the term “Outcomes” as used here refers to the analysis of data, the decision taken based on the analysis, or both. Proposed Change (if any): Clarify what is meant by “outcomes” in the context of the monitoring report.	
ICH 213 EMA 361		Proposed Change (if any): Add “to the sponsor” at the end of the sentence.	
ICH 261 EMA 407		Proposed Change (if any): Revise “Original data and records” to read “Original data and records, including electronic data….”	
ICH 299 - 302 EMA 444 - 446		Comment: ACRO recommends that “system” is defined to clarify whose system it pertains to, e.g., sponsor, investigator, ethics committee, competent authority, etc. Also, it is not clear if “consistent intended performance” includes reproducibility, therefore ACRO recommends adding this. Proposed change (if any): Clarify “system” ownership and refer to “consistent reproducible intended performance”	
ICH 342 - 344		Comment: It is recommended to indicate the hierarchy of	

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EMA 493 – 494		regulation, i.e. is privacy more important than e.g. maintaining controlled documents/audit trail. For example, when by accident patient identifiers are entered, can “hard delete” be accepted (meaning altering the audit trail) in order to delete the identifiers from audit trail? Proposed change (if any): Add text to clarify the precedence of regulation with regard to maintaining privacy and audit trails.	
ICH 469 - 470 EMA 639 – 640		Comment: ACRO recommends that “remote monitoring” should be added specifically to the text. It is the experience of ACRO member companies that many sites are producing SOPs that “prohibit” remote monitoring. These sites mistakenly think that this means faxing of source docs, or webex to review data in eSystems with sites on the phone. Proposed change (if any): Add “remote monitoring” to the text.	
ICH 477 - 478 EMA 649 – 650		Comment: ACRO recommends that the text should note specifically that this includes having sufficient time to review and remedy findings identified through monitoring. With the focus of risk-based monitoring largely on site processes, investigators will need to give appropriate time to process improvement. The benefit will be preventative actions across all trials and not isolated to individual issue	

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		resolution/correction. Proposed change (if any): Include text to clarify that this includes having sufficient time to review and remedy findings identified through monitoring.	
ICH 489 – 492 EMA 661 - 664		Proposed Change (if any): ACRO recommends adding “and compliance with the protocol and applicable regulations” at the end of the sentence.	
ICH 608 – 610 EMA 791 - 794		Comment: ACRO recommends that clarification is included that the term “written” also encompasses electronic records e.g. PDF, HTML, and should not be taken to infer “written on paper”. Electronic systems can automatically and accurately date consent forms. This addition of an electronic date stamp during the signature process should be considered equivalent to “personal” dating of the form. In the absence of this, it is hard to prove that the subject personally dated the electronic form. Furthermore, subjects and investigators are prone to dating errors. Proposed Change (if any): Clarify the term “written”, and that an electronic signature with automatic date stamp is acceptable.	
ICH 656 - 658 EMA 836 – 838		Comment: ACRO recommends that this section is expanded to clarify the requirement as there may be a conflict between	

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		regulatory procedures and the need to inform trial subjects of new information in a timely manner. For instance, some regulatory authorities require that a safety update in the Investigator Brochure is not to be implemented until after their approval. This appears to be in contradiction to informing of subjects in a timely manner, which should be clarified, and guidance given to the investigator how to use new safety information. Proposed change (if any): Clarify the requirement to remove the apparent conflict between regulatory procedures and the need to inform trial subjects of new information in a timely manner.	
ICH 665 – 670 EMA 845 - 851		Comment: ACRO recommends that, with the adoption of multimedia as part of the consent process, the trial subject should receive a copy of, access to, or a transcript from said multimedia. Proposed Change (if any): Add clarification that "…should receive a copy…" encompasses electronic consent forms. In such cases the forms can be emailed to the subject, printed for the subject or provided to the subject in other means accessible to the subject, e.g. portals, secure websites, phone apps. Where a subject does not have means to access the electronic forms, a printed copy should be provided.	

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ICH 705 - 709 EMA 886 - 891		Comment: “Adequate source documents” should be qualified as ‘(paper and/or electronic)’. Audit trails could be based on either paper or electronic source data and ACRO recommends that further guidance on audit trails should be included. In particular, the sentence “Changes to source data…..should be traceable” potentially refers to electronic source systems within hospitals, for example electronic health records. Where a hospital already has an electronic health record system, it may be the case that the system does not maintain an audit trail or change log. Without knowledge of how many EHR systems do not have audit trails, caution should be exercised about implementing this change. The impact could extend far beyond what is anticipated. Additionally, the statement “changes to source data pertinent to the clinical trial should be traceable, should not obscure the original entry and should be explained if necessary” should be clarified with regard to historical source data. While the statement accurately reflects best practice for data generated within the clinical trial, it is unlikely that all data generated outside of the clinical trial conduct (e.g., patient history) will meet these criteria. Proposed change (if any): Revise “Adequate source documents” to read “Adequate source documents (paper and/or electronic)” and include additional guidance on audit trails and on historical source data.	

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ICH 785 - 797 EMA 976 - 988		Comment: For the entire 5.0 Quality Management section, ACRO recommends that it should be considered and pointed out whether any of the considerations need to be implemented into the methods section for quality within the protocol and clinical study report (if this is the case, ICH templates would need updating). ACRO also recommends that the requirement that “the sponsor should identify those processes and data that are critical to assure human subject protection and the reliability of study result” should be expanded to explain how and if this information should be carried forward into the protocol and clinical study report. Proposed change (if any): Expand the requirement that “the sponsor should identify those processes and data that are critical to assure human subject protection and the reliability of study result” to explain how and if this information should be carried forward into the protocol and clinical study report.	
ICH 792 - 793 EMA 983 - 984		Comment: ACRO considers that including the concepts of systematic action (comprehensive and consistent) and risk assessment (proactive planning) would raise the level of quality during pre-study planning that would be consistent with regulatory expectations and therefore proposes the following revision Proposed change (if any): Revise the sentence to read as	

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		follows: “The methods used to assure and control the quality of the trial should be proportionate to the risks inherent in the trial and the importance of the information collected based upon a systematic risk assessment (as defined in subsection 5.01).”	
ICH 799 - 800 EMA 990 - 991		Proposed change (if any): Change “study results” to ‘all study results’	
ICH 805 EMA 995 - 996		Comment: This statement on risk identification should also include data processing as there is some risk during processing, e.g. data conversion, etc. Proposed change (if any): Add “data processing”.	
ICH 809 EMA 999		Comment: ACRO recommends that this statement should be expanded to provide guidance on how deletion and/or corruption of data should be addressed. Proposed change (if any): Expand the statement to provide guidance on how deletion and/or corruption of data should be addressed.	
ICH 821 - 822 EMA 1010 - 10111		Comment: ACRO agrees that detection of deviations from predefined quality tolerance limits should trigger an evaluation to determine if action is needed. However, it is not clear from the text to what extent the various parties involved in a	

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		clinical trial will be required to document the decision-making process with regard to the action to be taken, and the extent to which the traceability of decision-making should be documented. ACRO recommends that additional text is added to clarify expectations in this regard. Proposed change (if any): Add text to clarify the extent to which decision-making processes and traceability of decision-making should be documented.	
ICH 824 - 826 EMA 1013 - 1014		ACRO is concerned that the term stakeholders may be subject to different interpretations and suggests the following revision. Proposed change (if any): Replace “stakeholders” with “all relevant stakeholders (e.g., CRO, investigator, central laboratory, etc.)”	
ICH 828 EMA 1016		Comment: The term “periodically” is subjective and open to interpretation. ACRO recommends that what is meant by “periodically” is clarified. Proposed Change (if any): Clarify the meaning of “periodically”.	
ICH 855 - 856 EMA 1045		Comment: ACRO agrees strongly with the statement that “The sponsor should ensure oversight of any trial-related duties and	

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		functions carried out on its behalf" and fully supports the fundamental concept that the sponsor bears overall responsibility for the conduct and quality of a clinical trial.	
ICH 895 EMA 1089		Proposed Change (if any): Replace "SOPs" with "documented procedures".	
ICH 898 - 901 EMA 1092 - 1094		Proposed change (if any): Add the following sentence at the end of the section: "Documented records of such training should be maintained."	
ICH 903 - 905 EMA 1095 - 1097		Proposed Change (if any): Reword to read as follows: "Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of data or metadata (i.e., maintain an audit trail, data trail, edit trail)."	
ICH 906 EMA 1098		Proposed Change (if any): Reword to read as follows: "Maintain a security system that prevents and monitors unauthorized access to the data".	
ICH 1139 - 1147 EMA 1335 - 1343		Comment: ACRO recommends that this section should also explain how centralized monitoring methods should be recorded for inclusion in the final database for reporting (e.g., protocol deviations). Proposed change (if any): Include additional text to explain	

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		how centralized monitoring methods should be recorded for inclusion in the final database for reporting.	
ICH 1222 - 1223 EMA 1413 - 1414		Comment: ACRO welcomes the addition of centralized monitoring to the Monitoring section of the guideline. However, it is not entirely clear that such monitoring should also be documented and reported to the sponsor. Proposed change (if any): Revise the text to read as follows: “The monitor should submit a written report to the sponsor after each trial-site visit, trial-related communication and centralized monitoring activity, as defined in the monitoring plan.”	
ICH 1233 - 1237 EMA 1423 - 1426		Comment: The term ‘monitoring results’ is open to interpretation and should be more clearly defined. Additionally, it should be made clear that a monitoring report is required for both on-site and centralised monitoring activities, and what is meant by central monitoring report“ outputs”. ACRO also recommends that consideration should be given as to whether the findings of the ‘verification of compliance with monitoring plan’ needs to be included in the final study report and, if so, that guidance is provided on how this should be done.	

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		Proposed change: Define “monitoring results” and revise the text to read as follows: “Results of on-site and centralized monitoring activities should be provided to the sponsor (including appropriate….” If the verification of compliance with the monitoring plan is to be included in the clinical study report, additional guidance should be provided on how this should be done.	
ICH 1240 - 1248 EMA 1428 - 1434		Comment: It is not clear whether the Addendum text should be included in the methodology sections of the protocol and clinical study report. ACRO recommends that this is considered and clarified. Proposed change (if any): If the Addendum text is to be included in the methodology sections of the protocol and clinical study report, this should be stated.	
ICH 1283 - 1286 EMA 1466 - 1469		The term “significant” is subjective and open to interpretation. Therefore, ACRO recommends amending the text as suggested below. Additionally, any corrective action resulting in change to the study design/plan/conduct would need to be implemented into protocol amendments and/or documented in the study report. ACRO therefore recommends that a statement to this effect is included in this section. Proposed change (if any): Amend the text to read “When significant noncompliance is discovered which affects product	

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		quality; rights, safety or wellbeing of subjects; quality and/or integrity of data, the sponsor should perform a root cause analysis……", and add a statement to clarify that any corrective action resulting in change to the study design/plan/conduct will need to be implemented into protocol amendments and/or documented in the study report.	
ICH 1700 - 1701 EMA 1929 - 1930		Comment: ACRO welcomes the flexibility allowed by the statement "The sponsor should ensure that the investigator has control of and continuous access to the CRF data reported to the sponsor. The sponsor should not have exclusive control of those data." ACRO fully supports this position and has long been concerned by the position taken by some regulatory agencies that data generated in a clinical trial and which are held by the sponsor should be verifiable to a copy not held (or that has not been held) by the sponsor. It is ACRO's view that it should be permissible for the sponsor or a third party contracted by the sponsor to hold these data in an electronic system that provides continual access for an investigator, including editing rights, to data generated by that investigator, and which includes an appropriate data trail to demonstrate that any changes to such data have been authorised by the investigator or his/her authorised delegate. On completion of the trial, an electronic record of the investigator's data and the data trail can be made available to the investigator for archiving purposes. ACRO recommends that, in order to ensure the flexibility allowed by the proposed	

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		statement is not misunderstood, text is added to the guideline to clarify that such an approach is acceptable. Proposed change (if any): Add text to clarify that the sponsor or a third party contracted by the sponsor may hold data in an electronic system that provides continual access for an investigator, including editing rights, to data generated by that investigator, and which includes an appropriate data trail to demonstrate that any changes to such data have been authorised by the investigator or his/her authorised delegate, and that, on completion of the trial, an electronic record of the investigator's data and the data trail is made available to the investigator for archiving purposes.	
Section 8.2.19		Proposed change (if any): The term "Trial initiation monitoring report" should be expanded to include 'or equivalent document(s) meeting the purpose of this essential document.'	
Section 8.3.12		Comment: It is not clear what provisions, if any, are made for providing electronic consent in the section addressing "signed informed consent forms". Proposed change (if any): Add text to describe the requirements for electronic consent.	
Section 8.3.14		Comment: Text should be added to this section to explain requirements when electronic Case Report Form is used. The	

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		requirement to leave an independent copy of the CRF at the site is valid for a paper CRF, but more guidance on the expectations for electronic CRFs is required. Proposed change (if any): Add text to describe the requirements for electronic CRFs.	
		Thank you for the opportunity to comment on this “Draft ICH Guideline for good clinical practice E6(R2) (EMA/CHMP/ICH/135/1995).” Please do not hesitate to contact ACRO if we can provide additional information (knoonan@acrohealth.org or +1 202 464 9340).	

Please add more rows if needed.